

Attorney Docket No.: DRE-0067
Inventors: Laurencin et al.
Serial No.: 10/052,121
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REMARKS

Claims 1-3, 5 and 6 are pending in the instant application. Claims 1-3, 5 and 6 have been rejected. Claim 1 has been amended. Support for amendments to claim 1 are provided in the specification at page 7, line 25 through page 8, line 15, page 9, lines 4-13, page 10, lines 18-22, and page 13, lines 9-14. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejection of Claims under 35 U.S.C. § 35 U.S.C. 103(a)

Claim 1 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Starling et al. (U.S. Patent 6,210,715) in view of Crotts et al. The Examiner suggests that it would have been obvious to use as the polymeric hollow microspheres of Starling et al. the hollow microspheres made from PLGA disclosed by Crotts et al. to obtain the property of PLGA having versatile biodegradability and biocompatibility as disclosed by Crotts et al. Further the Examiner suggests that it would have been expected that the PLGA hollow microspheres can be bonded together to form an aggregate of hollow microspheres by procedures disclosed by Starling et al. The Examiner suggests that the aggregate, when shaped as disclosed by Starling at col. 9, lines 50-58), will be a scaffold as presently claimed.

Claims 2, 3, 5 and 6 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1, and further in view of Spaulding (U.S. Patent 6,001,643) and Granet et al. (reference AJ on 1449). The Examiner suggests that, when preparing the aggregate of bonded together hollow

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microspheres of Starling et al. using the hollow microspheres disclosed by Crotts et al., it would have been obvious to use the aggregate for cell culture as suggested by Starling et al. and carry out cell culture in a roller bottle as disclosed by Spaulding or in a rotating-wall vessel as disclosed by Granet et al. since the culturing techniques are intended for culturing cells on a carrier.

Applicants respectfully traverse these rejections.

MPEP § 2143 sets forth three basic criteria which must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations.

The cited combinations of references do not meet these criteria with respect to the instant invention.

In particular, the PLGA microspheres taught by Crotts et al. range in size from approximately 30 μm to 350 μm . See Figure 2 of Crotts et al. Further, as taught at page 98 of Crotts et al. larger microspheres prepared from formulation D with sizes ranging up to 350 μm had highly porous surfaces characterized by Crotts et al. as a 'sponge-like' porous structure.

In contrast, microspheres used in the scaffolds of the present invention are larger, preferably ranging in size from 500 to 860 μm . See teachings at page 7, line 25 through page 8, line 15 of the instant specification. Further, as taught at page 9,

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lines 9-13 of the instant specification, the network of pores of the scaffold formed by the microspheres are interconnected, thus indicating that the microspheres themselves are not porous nor 'sponge-like'.

Thus, contrary to the Examiner's suggestion, substitution of the PLGA microspheres of Crotts et al. into the scaffolds of Starling would not result in the instant invention.

Further, Starling et al. teach the density of their scaffold to be equal to water or greater. See specifically, col. 6, lines 57-60 of Starling. In contrast, scaffolds formed with microspheres in accordance with the present invention are lighter than or light as water. See teachings in specification at page 9, lines 4-8, page 10, lines 18-22 and page 13, lines 9-14.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to include the distinguishing features of different pore size, different porosity of the microspheres and different density of the resulting scaffold. Support for these amendments is provided in teachings in the specification at page 7, line 25 through page 8, line 15, page 9, lines 4-13, page 10, lines 18-22, and page 13, lines 9-14.

Since the combination of references by Starling et al. and Crotts et al. would not result in a scaffold with the characteristics of the instant claimed scaffold and neither teaches nor suggests a scaffold with these claim limitations, this combination of references cannot render prima facie obvious claim 1 as amended.

Further, the secondary references cited by the Examiner in the rejection of dependent claims 2, 3, 5 and 6, namely Spaulding

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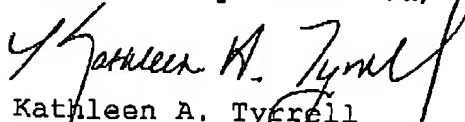
(U.S. Patent 6,001,643) and Granet et al., fail to remedy the deficiencies in teachings of Starling et al. and Crotts et al. with respect to the instant claimed invention. These references are related to cell culturing methods. They are not related to a scaffold formed from hollow microspheres as set forth in claim 1. Thus, claims 2, 3, 5 and 6 which depend from claim 1 are also nonobvious over the cited combination of references. See MPEP 2143.03.

Withdrawal of these rejections under 35 U.S.C. 103 is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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